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In The
Supreme Court of the United States

EBAY INC. AND HALF.COM, INC.,

Petitioners,

v.

MERCEXCHANGE, L.L.C.,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF THE ASSOCIATION OF AMERICAN UNIVERSITIES AND THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES AS AMICI CURIAE IN SUPPORT OF RESPONDENT

MORGAN CHU
LAURA W. BRILL*
JASON SHEASBY
RICHARD SIMON
ADAM HIME
IRELL & MANELLA LLP
1800 Avenue of the Stars
Los Angeles, California 90067
(310) 277-1010
Counsel for Amici

Counsel of Record

March 10, 2006

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

The Association of American Universities ("AAU") was founded in 1900 by a group of fourteen universities offering the Ph.D. degree. The AAU currently consists of sixty-two leading research universities in the United States and Canada. The association assists members in developing national policy positions on issues that relate to academic research, graduate and professional education, as well as issues relating to the transfer of innovative technology from university to industry.

The National Association of State Universities and Land-Grant Colleges ("NASULGC") was founded in 1887 and is the nation's oldest higher education association. Its members include public universities, public-university systems, and land-grant institutions from all 50 states, the U.S. territories and the District of Columbia.

Among the top 100 recipients of federal funds for research and development, eighty-three are AAU/NASULGC affiliated institutions. These eighty-three institutions conducted approximately seventy-five percent of all federally funded academic research and development in 2002, the last year for which published data are available.

Amici and their members have provided testimony in numerous congressional hearings relating to intellectual property and technology transfer issues affecting research universities. *Amici* have an interest in the proper application of the Bayh-Dole Act (P.L. 96-517, Patent and Trademark

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[1] The parties have consented to the submission of briefs of *amici curiae* in letters filed separately with the Clerk of the Court on December 15th and 21st, 2005, by counsel for Petitioner and Respondent, respectively. Pursuant to Rule 37.6, counsel for *amici curiae* certify that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amici curiae*, or their counsel, has made a monetary contribution to this brief's preparation or submission.

Law Amendments Act of 1980), the unique statutory scheme that allows research universities and other nonprofit organizations and small businesses to retain patent rights to inventions derived from federally funded research projects. The Bayh-Dole Act is aptly praised as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century" because it has "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money" and "[m]ore than anything, . . . [has] helped to reverse America's precipitous slide into industrial irrelevance." *Innovation's Golden Goose*, The Economist, Dec. 14, 2002, at 3.

University technology transfer efforts promoted by the Bayh-Dole Act would function less effectively without the availability of injunctive relief in cases of patent infringement. In addressing the appropriate standards for the issuance of injunctions in patent cases, the Court should take care not to upset the delicate, well considered, and well functioning legislative scheme that facilitates the transfer of significant scientific advancements from university laboratories to the public at large.

Another goal of *amici* is to educate the public about the important role of higher education and scientific research in American society. Much research performed by universities affiliated with *amici* is directed to core issues at the forefront of basic science. Groundbreaking university research is later developed—through substantial investment by licensees—into products with wide public benefit. Because universities are core participants in the advancement of science, they should not be disadvantaged in their patent rights—including the right to injunctive relief—either because they license their inventions to others or because they do not engage in direct product development themselves.

SUMMARY OF THE ARGUMENT

1. By express Congressional authorization, universities, and other organizations that pursue scientific research with the aid of federal funds, have authority to patent the inventions resulting from such research. This authority was granted in the Bayh-Dole Act, a unique and phenomenally successful statutory scheme aimed at ensuring the effective transfer of federally funded technological advancements from university to industry for development into products and processes that benefit society.

The Bayh-Dole Act was enacted against the background of established law favoring the grant of injunctions for patent infringement. The Bayh-Dole Act also specifically avoided establishing a default compulsory license regime for federally funded patentable inventions. Instead, Congress established a special administrative procedure for ensuring that the availability of injunctive relief and the rights of exclusion that are fundamental to patent ownership would be adequately constrained. Whatever rule the Court may announce in the unique circumstances of this case, the Court should make clear that it does not intend to upset the careful balance Congress has struck to regulate the degree of exclusivity that universities enjoy in patents derived from federally funded research.

For example, as a result of the Bayh-Dole Act, universities have a strong incentive to enter licensing agreements or other relationships with private businesses, including start-up companies, to develop and commercialize the fruits of their research. The value of these arrangements, as well as the incentives for university innovation, would be diminished by any rule holding that the willingness to license or the lack of direct product development by an inventor weighs against issuance of a court injunction upon a finding of infringement. As a general matter, the willingness of a patentee to grant licenses should not be held against the

patentee in seeking an injunction against infringers. Nor should the fact that that a university or other non-profit organization relies on others to make products practicing the invention rather than engaging in direct product development count against such organization in determining whether to grant an injunction in cases of patent infringement.

2. Even setting aside the Bayh-Dole Act, scientific research at universities is at the very core of what the patent laws of this country were designed to protect. The work of university researchers is often at the forefront of scientific awareness. Frequently the inventions are so fundamental that there is no ready market to which they can be immediately applied. Rather, putting these inventions to practical use and developing products based on them can require years of additional research and development, often by start-up companies taking great financial risks. Because this work is so fundamental to scientific advancement, it would merit strong patent protection, including the availability of injunctive relief, even without the special statutory scheme of Bayh-Dole.

Finally, the practices of universities raise none of the concerns regarding abuse of patent rights that are at the basis of calls for far-reaching patent legislation reform and changes in the standards for issuance of injunctive relief. Universities make material contributions to the advancement of knowledge and funnel royalties back into further research. Their scientific research is at the core of efforts to develop many advanced technologies. They do not merely buy the patents of others and seek to exploit them against those who have developed similar solutions. Universities convey licenses and are involved in the creation of start-up enterprises to fulfill their obligations in connection with receipt of federal funds and to bring basic advancements to the public in the first instance. They do not hold back their inventions from public use to create anti-competitive effects and protect their own market position. Indeed, they generally

do not have any product in the market to protect. Thus, many factors that might influence the equitable decision of whether to grant an injunction in cases of abusive practices simply do not apply to universities.

ARGUMENT

I. THE BAYH-DOLE ACT CREATES A UNIQUE STATUTORY SCHEME GOVERNING THE PATENT RIGHTS OF FEDERALLY FUNDED RESEARCH EFFORTS AND IS PREMISED ON THE AVAILABILITY OF INJUNCTIVE RELIEF

A. Prior to the Bayh-Dole Act, Federally Funded Scientific Research Rarely Made Its Way to Consumer Products

Before the enactment of The Patent and Trademark Law Amendments Act of 1980, commonly known as the Bayh-Dole Act, the federal government lacked a unified federal technology transfer policy. Absent special agreements, titles to patents covering inventions derived from federally funded research were held by the federal government. The lack of a unified structure for the government to license its patents resulted in a huge surplus of unlicensed, government-owned patents, despite efforts to streamline government patent-policy. Lacy, Brown & Rubin, *Technology Transfer Laws Governing Federally Funded Research and Development*, 19 Pepp. L. Rev. 1, 9 (1991). In addition, the private sector was not keenly interested in licensing government patents because non-exclusive licenses to government inventions offered little incentive to invest in the commercialization of the invention, and exclusive licenses were difficult to come by for bureaucratic and political reasons. *Id.* *See also* United States General Accounting Office Report to Senate Comm. on the Judiciary and House Comm. on the Judiciary, Technology Transfer: Administration of the Bayh-Dole Act by Research Universities 2 (May 1998) (hereinafter *1998 GAO Report)*

(noting that those seeking to utilize federally-owned patents faced numerous regulatory barriers that made commercial development difficult, if not impossible).

B. The Bayh-Dole Act Allows Universities to Patent Inventions Derived from Federally Funded Research, Encourages Technology Transfer, and Is Premised Upon the Availability of Injunctive Relief.

The Bayh-Dole Act dramatically reformed U.S. patent policy with respect to government-sponsored research by establishing uniform procedures to allow universities, non-profit institutions, and small businesses to obtain title to inventions discovered through federally funded research. P.L. No. 96-517 (Dec. 12, 1980) (codified at 35 U.S.C. § 200-212). In granting universities ownership of their inventions, the legislation envisioned universities licensing and forming partnerships with the private sector to enable "private industry to utilize government funded inventions through the commitment of risk capital necessary to develop such inventions to the point of commercial application" H.R. Rep. No. 96-1307, pt. 1, at 3 (1980).

The Bayh-Dole Act applies to all research conducted under federal funding arrangements with universities and other identified institutions. Key terms of such funding arrangements are dictated by the Act and its implementing regulations, and these terms delineate the rights and responsibilities of the research contractor and the funding agency. 35 U.S.C. §§ 201(b), 202; 37 C.F.R. § 401.1 *et seq.* (1987). Under 35 U.S.C. § 202, for example, academic institutions and other non-profit contractors may elect to take title to their inventions. If they do take title, they are required to seek patent protection for the invention, *id.* at § 202(c)(3); to grant the government a non-exclusive, non-transferable, paid-up right to practice the invention throughout the world, *id.* at § 202(c)(4); to favor United States industry in licensure of their patents, *id.* at § 202(c)(8), 204; and to comply with

disclosure and periodic reporting requirements, §§ 202(c)(1)-(c)(3), (c)(5), (c)(6).

The Bayh-Dole Act also addresses the educational and research obligations of universities and ensures that individual inventors receive adequate incentives and rewards. For example, 35 U.S.C. § 202(c)(7) specifies that government funding agreements shall include language providing for patent royalties to be shared with the inventor of the subject patent. The statute also requires that the remaining income, after the payment of expenses, be used to support further scientific research or education. *Id.* *See also* 37 C.F.R. §§ 401.3, 401.14(k)(2) and 401.14(k)(3) (regulations governing content of funding agreements and distribution of royalty income). Thus, the Bayh-Dole Act and its regulations are carefully crafted to reward innovation and to support further research in upholding the Constitutional mandate to promote the "Progress of Science."

i. The Federal Government's "March-In" Right Under Bayh-Dole Strikes a Legislative Balance, Providing Incentives for Innovation and Promoting Public Access to Inventions.

The Bayh-Dole Act includes express provisions to balance the public's interest in the fruits of federally funded research against the goal of providing incentives to innovators. In doing so, the Act declines to implement a mandatory licensing scheme as a default regime to promote the diffusion of inventions. Instead, 35 U.S.C. § 203 contains a unique "march-in right" for the federal government in the event that a university or other covered entity does not undertake adequate efforts to achieve the practical use of a patented invention. This march-in right is the means that Congress chose to ensure that inventions derived from federally funded research would be adequately disseminated to the public consistent with the need to provide adequate incentives to university and other non-profit researchers to innovate. The march-in right exists against the background

law governing the availability of injunctive relief. Indeed, legislators recognized that the Bayh-Dole Act would confer a "type of monopoly privilege" on universities. H.R. Rep. No. 96-1307, pt. 1, at 30 (1980) (statement of Congressman Jack Brooks).

Under 35 U.S.C. § 203, in the event that the patentee and its licensees are not acting diligently in achieving the practical application of the patented invention, the funding agency, subject to procedural safeguards that protect the rights of the universities, may take specific action to promote the diffusion of the patented invention.[2]

Under Section 203(a) the federal agency

> shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, and assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or

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[2] The government may march in on a university or related non-profit institution only in the narrow circumstances when:

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204. 35 U.S.C. § 203(a).

> applicants, upon terms that are reasonable under the circumstances.

35 U.S.C. § 203(a). If the "contractor" refuses, the federal agency may grant such license itself. *Id.* Any agency exercise of its march-in right is subject to appeal in the United States Court of Federal Claims. 35 U.S.C. § 203(b).

The march-in right exists against, and would not be necessary but for the background principles of law making available injunctive relief in cases of patent infringement. Moreover, by specifically referring to "partially exclusive" and "exclusive license[s]," Congress must have understood and intended for true exclusivity—enforced through injunctions—to be an available option.

The march-in right is also significant because it provides a strong incentive for universities to diligently pursue licensing and other opportunities for commercial development. Thus, the Bayh-Dole Act fully addresses in the context of universities and others engaged in federally funded research, concerns that the threat of injunctive relief could be used to deprive the public of important inventions. Moreover, any rule of law that limits the availability of injunctive relief to universities as willing licensors would undermine the careful balance of rights enacted in the Bayh-Dole Act, with its emphasis on licensing.

ii. Congress Enacted Bayh-Dole Against a Legal Backdrop That Did Not Discriminate Against Non-Commercial Researchers in the Granting of Injunctive Relief

The remedy of injunctive relief in cases of patent infringement was well established at the time the Bayh-Dole Act passed, and was not dependent on whether the patent owner made a product claimed in the patent. Indeed, ever since the *Continental Paper Bag* case, this Court has consistently held that the right to injunctive relief does not turn on whether the patent owner itself makes products

covered by the claimed invention. *See Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908) (noting that the "exclusive Right" given by the Constitution to patent owners is not dependent upon commercial use of the invention); *see also Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 34 (1923) (same); *Woodbridge v. United States*, 263 U.S. 50, 55 (1923) (same); *Fox Film Corp. v. Doyal*, 286 U.S. 123 (1932) (same); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 433 (1945); *Special Equipment Co. v. Coe,* 324 U.S. 370, 378-79 (1945).

Although these cases have been criticized as allowing a company to engage in anti-competitive practices by holding back patents that it is not using, no such concern exists with respect to federally funded research by universities. Universities have no incentive to hold back their inventions. They exist to discover and disseminate new knowledge; they advance scientific understanding, providing the foundation for innovative commercial development. In addition, they earn financial returns on their technology only if they license it to others. And to guard against any contrary behavior, the federal government retains the march-in right.

For all these reasons, the rights accorded to universities under the Bayh-Dole Act must be understood to incorporate the long-established principle that injunctive relief is available without regard to a patentee's own commercial exploitation of a patent. *Cf., Lindahl v. Office of Personnel Management*, 470 U.S. 768, 782-83 (1985) ("[T]he fact that Congress amended § 8347 in 1980 without explicitly repealing the established Scroggins doctrine itself gives rise to a presumption that Congress intended to embody Scroggins in the amended version of § 8347."). Indeed, as recently as 2005, Congress has considered broad changes to the availability of injunctive relief, but has continued to allow existing doctrine to stand. *See, e.g.*, "Patent Act of 2005" H.R. 2795, 109th Cong. (2005); *Legislative Hearing on H.R.*

2795, the "Patent Act of 2005," House Jud. Comm. (June 9, 2005).

Considerations of *stare decisis* have special force where property rights are concerned and where investments and contractual arrangements have evolved against settled principles of background law. *United States v. Title Insurance & Trust Co.*, 265 U.S. 472, 486-87 (1924) ("[I]t is of great importance to the public that, when [questions affecting title to property] are once decided, they should no longer be considered open. Such decisions become rules of property, and many titles may be injuriously affected by their change."). Only Congress may enact a prospective rule changing the nature of the property right or remedies available for infringement without upsetting existing expectations.

Because any substantial change to the standards for injunctive relief entails complex economic and policy considerations, Congress is the most appropriate body to adopt a change in law. Congress made no such change in enacting the Bayh-Dole Act, instead using the march-in right to balance competing policy considerations. This Court should not upset the delicate balance Congress struck in enacting the Bayh-Dole Act. In addition, because federally funded research is subject to the Bayh-Dole Act, the willingness of universities to grant licenses to their inventions or to rely on others for commercial development should not be factors weighing against the grant of injunctive relief.

C. The Bayh-Dole Act Has Been Phenomenally Successful in Bringing the Bounty of Federally Funded Research to Consumers

By nearly every account, the Bayh-Dole Act has been phenomenally successful in fostering partnerships between the private sector and universities, in creating commercial applications of government funded research, and, ultimately, in stimulating growth and productivity of the American

economy.[3] As *The Economist* succinctly described it, Bayh-Dole has "helped to reverse America's precipitous slide into industrial irrelevance." *Innovation's Golden Goose*, The Economist, Dec. 14, 2002 at A3. The passage of the Bayh-Dole Act has fueled a technology transfer from the academic community to the private sector that has resulted in an unprecedented period of technological innovation of widespread benefit to the public. Universities and their researchers have benefited from royalty income on their inventions. The government and the public have benefited because more government-funded technology has been brought into commercial use. And the growth of university licensing activity has benefited the overall economy. *See 1998 GAO Report* at 15.

Because of the Bayh-Dole Act, the number of patents annually issued to universities skyrocketed from 250 in 1980, to 1,600 by 1993, to over 3,680 in 2004. *See* Association of University Technology Managers, *AUTM U.S. Licensing Survey, FY 2004: Survey Summary* 2 (Ashley J. Stevens, ed., 2005) (hereinafter *2004 AUTM Survey*). In some years, eighty percent of patents resulted from federally funded research. Kenneth Dueker, *Bio-business on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 Food Drug L.J. 453, 508 (1997). Thirty billion dollars of economic activity each year and over 250,000 jobs can be attributed to the commercialization of academic research. Q. Todd Dickinson, Assistant Secretary of Commerce and Commisioner of Patents and Trademarks, Remarks to The National Academies: Board of Science,

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[3] *See, e.g.*, Rebecca Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1708 n.185 (1996) (quoting statements made during *The Bayh-Dole Act, a Review of Patent Issues in Federally Funded Research: Hearings on Pub. L. No. 96-517 Before the Subcomm. on Patents, Copyrights and Trademarks*, Sen. Jud. Comm., 103d Cong., 1-2 (1994)).

Technology and Economic Policy (Feb. 2, 2000), *transcript available at* http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/academies.pdf. Between 1980 and 2001, 2,922 new companies have formed based on a license from an academic institution. Howard Bremer, Presentation to NASULG: The First Two Decades of the Bayh-Dole Act as Public Policy (Nov. 11, 2001), *transcript available at* http://www.nasulgc.org.

Universities have effectively licensed numerous revolutionary technologies such as Harvard's heart-imaging contrast formulations, University of California's cochlear implants for congenital deafness, Stanford's cancer-detecting synthetic proteins, University of Arkansas' vaccine for avian viruses, Yale's HIV antiretroviral drugs, and MIT's public key data encryption techniques.[4] Government-funded, university-driven technology transfer has given society extraordinary products such as the following:

- One of the greatest advancements in biotechnology in the last few decades is cotransformation, a process invented by three Columbia University researchers that enables the

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[4] *See 1998 GAO Report* at 18-19, 66; AUTM, *Technology Transfer Works: 100 Cases from Research to Realization* 12 (2006), *available at* http://betterworldproject.net; Yale University Office of Cooperative Research, *Bringing Ideas to Life 1982-2002* at 3, *available at* http://www.yale.edu/ocr/images/2002.ocr.annual.report.pdf. *See also* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tul. L. Rev. 631, 636 (2001) ("Government-funded basic research has been largely responsible for the emergence and growth of the biotechnology industry."); Council on Governmental Relations, *University Technology Transfer: Questions and Answers* (Nov. 30, 1993), *available at* http://www.cogr.edu/docs/BayhDoleQA.htm ("Core technologies, likely to spark whole new industries, often result from university patents.").

production of life-saving proteins in living cells. Leading therapeutics for stroke, hemophilia, asthma, lymphoma, multiple sclerosis, and arthritis would not exist today without the cotransformation process. AUTM, *Technology Transfer Works: 100 Cases from Research to Realization* 52 (2006), *available at* http://betterworld-project.net.

- The twenty million Americans who suffer from diabetes can manage the disease more effectively with a wristwatch that monitors their blood-sugar levels without the need to pierce the skin. The watch utilizes a non-invasive glucose monitoring technique invented at the University of California, San Francisco and licensed to Cygnus, Inc. AUTM, *Technology Transfer Stories: 25 Innovations That Changed the World* 56-58 (2006), *available at* http://betterworldproject.net.

- Google, the wildly popular Internet search engine that handles over eighty percent of all search requests, started as a federally-supported research project at Stanford University. Stanford licensed the patent to the revolutionary search algorithms to a start-up founded by the original researchers: today Google, Inc. is a multibillion dollar company. AUTM, *Technology Transfer Stories: 25 Innovations That Changed the World* at 40-42.

The application of university research to pharmaceutical development alone has produced advanced treatments such as: Activase (heart attack and stroke), Allegra (allergies), Avonex (multiple sclerosis), Benefix (hemophilia), Caltrate Colon Health (colon cancer), Enbrel (rheumatoid arthritis), Epogen (anemia, hemophilia, cystic fibrosi), Hepatitis B vaccine, HIBTiter (Haemophilus influenzae, a leading cause of meningitis in children), Humira (rheumatoid arthritis), Leukine (Crohn's Disease), Macugen (degenerative eye disease), Panretin (AIDS-related Kaposi's sarcoma), PSA

Test (prostate cancer), Rebif (multiple sclerosis), Rituxin (non-Hodgkin's lymphoma), Simulect (kidney transplantation), Surgisis (soft tissue damage), Synagis (respiratory synectial virus), Taxol (breast and ovarian cancers), Thryogen (thyroid cancer), transdermal nicotine patch (smoking addiction), Xolair (asthma), Zenapax (organ transplantation). AUTM, *Technology Transfer Works: 100 Cases from Research to Realization.*

Ensuring that patentees can prevent unlicensed parties from practicing their inventions is a significant protection that has helped to make these achievements possible. Under the district court's reasoning in this case, however, the fact that universities themselves have not made the commercial products described above but have engaged in licensing to others would count against the universities in obtaining injunctions against infringers. Such a result is far outside anything Congress intended in enacting the Bayh-Dole Act and has no basis in the sound application of principles of equity.

II. THE AVAILABILITY OF INJUNCTIVE RELIEF PLAYS AN IMPORTANT ROLE IN UNIVERSITY TECHNOLOGY TRANSFERS

A. Effective Technology Transfer and Licensing Depend on the Availability of Injunctions in Cases of Infringement

As explained above, the Bayh-Dole Act sought to address significant problems in technology transfer. The lack of an ownership interest in their inventions discouraged federally funded universities from seeking avenues for commercialization of their scientific advancements. In addition, companies did not make substantial investments to develop products based on patents available through the federal government because of the potential inability to protect their investment.

The availability of injunctive relief in cases of infringement of university-owned patents after Bayh-Dole plays an important role in effective technology transfer arrangements of universities. For example, many universities license their inventions through non-exclusive licenses. The willingness of licensees to enter into such arrangements is likely to be substantially diminished if the university's access to injunctive relief is reduced. This is because non-exclusive licensees lack standing to bring infringement actions. *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1553 (Fed. Cir. 1995) (*en banc*) ("The grant of a bare license to sell an invention ... does not provide standing without the grant of a right to exclude others."), *cert. denied*, 516 U.S. 867 (1995). Such licensees must rely on the patent owner to pursue cases of infringement. Yet, if the university cannot obtain an injunction precisely because it is willing to license its technology and has not commercialized the product itself, the value of a non-exclusive license will be diminished, as will be the incentive of such licensees to make substantial financial investments to develop products under such a license.

In the absence of injunctive relief, the outcome of litigation would often put an infringer in no worse position than if it had decided to take a license. The remedy in most cases would be a reasonable royalty. As a result, infringers would have a strong incentive to risk litigation, since the end result would not be substantially worse than paying a license up front, and they might be able to obtain a competitive advantage while litigation was pending. The willingness of companies to take such a risk is enhanced when the patent owner is a university or other non-profit organization because such institutions generally do not have a stream of income from the sale of commercial products to support patent enforcement litigation efforts.[5]

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[5] For example, in fiscal year 2004, Harvard spent only 2% of its licensing revenue on legal expenses, which covered only part of the

As a result of the practical difficulties universities would face in enforcing their patents in the absence of injunctive relief, the value of licenses they might offer would be radically reduced. Authorized licensees could have no comfort that unauthorized use by others could be brought to a stop. Their own licensing payments would put them at a competitive disadvantage against infringers who were willing to risk detection and enforcement.

Universities would be put in the position of allowing infringement to continue while maintaining their existing commitments to research and education or redirecting their budgets to patent enforcement on the speculative hope that they might, years later, recover royalties sufficient to cover the litigation expense. Only in "exceptional cases" are attorneys' fees available in patent infringement suits. 35 U.S.C. § 285. Treble damages are available only for willful infringement, and even when juries find willfulness, judges retain discretion not to enhance damages. *Rite-Hite Corp. v. Kelley Co., Inc.*, 819 F.2d 1120, 1126 (Fed. Cir. 1987). The limited availability of these remedies to a narrow class of cases suggests that they were not intended to be the sole means of effectively granting the right to exclude, which exists as to all patents. 35 U.S.C. § 154(a)(1). Moreover, the relative effectiveness of treble damages, attorneys' fees, and injunctive relief in creating appropriate deterrents for patent infringement is a complex policy choice that depends on empirical evidence outside the reach of this Court on the record in this case and is appropriately left to the discretion of Congress.

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fees incurred by outside counsel in prosecuting (not enforcing) its patents. *See* Harvard University Office for Technology and Trademark Licensing, *Annual Report to the Committee on Patents and Copyrights Fiscal Year 2004* at 5, *available at* http://www.techtransfer.harvard.edu/files/OTD_AR2004.pdf.

It would be a distortion of the role of the research university to insist that it create a product as a predicate to excluding unlicensed parties from practicing its patented inventions. Yet the district court's ruling in this case, if taken to an extreme, seems likely to lead to such a result. The focus of the university is and always has been to undertake "basic research that may not lead to the creation of new and profitable products or services in the near term." *1998 GAO Report* at 2.[6] Universities rarely operate in a commercial market; instead, they transfer the results of their basic research to the commercial sector for development. Congress clearly contemplated this partnership between scholarship and industry in passing the Bayh-Dole Act, and the Act has greatly facilitated the useful transfer of university research into the commercial sector through university patenting and licensing to companies. This technology transfer has produced enormous benefits to society in the form of new products and processes. Weakening the rights of universities as patentees would only serve to undermine a collaborative system that has worked for decades.[7]

Finally, the incentives of start-up companies to enter into arrangements with universities and make substantial investments under even exclusive licenses could be substantially diminished if injunctive relief were unavailable except to those who already have a product developed. Many companies will not be willing to make the necessary investment even under an exclusive license if the fact that a

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[6] *See also* Howard W. Bremer, Presentation to NASULGC: The First Two Decades of the Bayh-Dole Act as Public Policy (Nov. 11, 2001) ("The generation of [patentable] inventions is almost never the main objective of basic research.").

[7] A system in which unauthorized users pay only a reasonable royalty and continue their practices is even less favorable to patentees than compulsory license schemes that Congress has repeatedly rejected.

competitor gets to market first would mean that an injunction were unavailable because the product of the licensed party had not yet come to market.

B. University Technology Transfer Programs Do Not Raise Concerns Regarding Abuse of Patent Rights.

Legitimate concerns regarding the abuse of injunctive relief by some patent holders do not apply to university licensing practices. Most fundamentally, universities make substantial scientific advances. In most cases, their licensing activity takes place before any product has been developed. They do not merely purchase patents from third parties to assert against existing industries that have already developed products. Universities seek to transfer their technology to industry. They do not hold back their inventions for anti-competitive reasons to protect an existing revenue stream on inferior products. Universities funnel royalty income back into scientific research and to inventors. They do not simply pay the income out in profits to investors. In seeking to transfer their technological developments to third parties to engage in product development, universities are not using their patents as "submarines" waiting for an industry to develop that can later be forced to pay very high settlement demands having made years of investment based on non-assertion of a patent-holder. If a university were to unreasonably withhold its invention from development, the Bayh-Dole Act explicitly provides the safety valve of "march-in rights." *See* 35 U.S.C. § 203.

Thus, while it may be the case that so-called "patent trolls" who do not make significant scientific advancements misuse the patent system by exploiting the availability of injunctive relief, any measures to deal with such misuse should be tailored to the problems associated with such misuse. Universities are not patent trolls.

CONCLUSION

For the foregoing reasons, the standards for obtaining injunctive relief in cases of patent infringement should recognize the unique circumstances of universities and others that operate under the Bayh-Dole Act. Such institutions generally license their inventions and do not make products themselves. Given that the Bayh-Dole Act contemplates the availability of injunctive relief for universities, and encourages them to license their inventions to others for development, the fact that a university engages in willing licensing and does not develop its own products cannot be weighed against the grant of an injunction in cases of patent infringement.

Respectfully submitted,

Morgan Chu
Laura W. Brill*
Jason Sheasby
Richard Simon
Adam Hime
Irell & Manella LLP
Counsel for Amici Curiae

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* *Counsel of Record*